510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

NOV - 4 2005

1. GENERAL INFORMATION

Trade Name	LIGAFIX® Resorbable Interference Screw
Common Name	Bone Fixation Screw
Classification Name	Screw, Fixation, Bone
Class	II
Product Code	HWC
CFR section	21CFR 888.3040
Device panel	Orthopedic
Legally marketed predicate devices	BioLok® Screw K002070 (Biocomposites Ltd) BIOSORB® Resorbable Void Filler K021963 (SBM)
Submitter	SCIENCE FOR BIOMATERIALS Sciences et Bio Matériaux ZI du Monge F 65100 LOURDES - FRANCE Owner operation Number : 9063735
Contact	Denis CLEMENT, General Manager Tel : +33 (0)5 62 42 21 01 Fax : +33 (0)5 62 42 21 00 e-mail : denis.clement.sr@wanadoo.fr Regulatory contact: Idée Consulting (FRANCE) Isabelle DRUBAIX e-mail : idrubaix@nordnet.fr

2. DEVICE DESCRIPTION

LIGAFIX® is a resorbable cannulated screw designed for the interference fixation of grafts in anterior cruciate ligament reconstruction. LIGAFIX® interference bone screw is made of a 30% ceramic (β-TCP) / 70% polymer (Poly Lactic Acid -PLA) (by weight) composite. LIGAFIX® interference bone screws are supplied sterile and individually packaged in double heat sealed pouches. LIGAFIX® screws present a socket which accepts a screwdriver of triangular cross-section that inserts deep into the core of the screw, to produce improved torque distribution.

3. INTENDED USE

LIGAFIX® is indicated for use in anterior cruciate ligament reconstruction to provide interference fixation of grafts.

4. PERFORMANCE DATA

Biological, mechanical and biocompatibility tests have been performed. Results confirmed that LIGAFIX® screws are highly biocompatible and presents the requisite strength to provide sustained fixation of the graft. LIGAFIX® screws strength retention profiles are compatible with the healing process.

5. SUBSTANTIAL EQUIVALENCE

LIGAFIX® is substantially equivalent to its predicate device BioLok® in terms of intended use, material, design and function.

Revised version: October 13, 2005

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 4 2005

Mr. Denis Clement
General Manager
Sciences et BioMatériaux
ZI du Monge
F 65100 Lourdes
FRANCE

Re: K050407
Trade/Device Name: LigaFix® Resorbable Interference Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: October 17, 2005
Received: October 24, 2005

Dear Mr. Clement:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K050407

Device Name: LIGAFIX® RESORBABLE INTERFERENCE SCREW

Indications for Use:
LIGAFIX® is a cannulated, sterile, single-use, resorbable interference bone screw made of a mixture of tri calcium phosphate (β-TCP) and Poly Lactic Acid (PLA) designed for the interference fixation of grafts in anterior cruciate ligament reconstruction.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

000004

510(k) Number K050407